

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

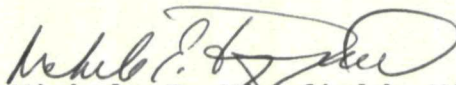
ANTIMICROBIAL PROGRAM BRANCH

EFFICACY REVIEW - FORM 1

Date EPA Received: 23 August 1996 Date EETMS Received: 23 August 96

Project Return Date: 19 February 97 Review Start Date: 6 Sept 1996

Review Completion Date: September 6, 1996

Reviewed By:  Michele E. Wingfield, Microbiologist

Lan Code: 1043-92A.609

EPA Reg. No. or File Symbol: 1043-92

EPA Petition or EUP No.: NONE

Product Type: Hospital Disinfectant

MRID No(s): NONE

Product Manager & Team No.: PM-32 (D. Aviado)

Product Name: LpH se

Company Name: Convatec-Div. of E.R. Squibb & Sons, Inc.

Submission Purpose: Review of Use Dilution Data from NCDA
Constable Lab (sample # 042596F28950106B
Batch # 210322)

Product Formulation: Liquid, to be diluted prior to use.

<u>ACTIVE INGREDIENT(S)</u>	<u>%</u>
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o-phenylphenol	7.3
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p-tertiary amylphenol	7.4
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ACTIVE INGREDIENT(S)

%

o-phenylphenol 7.3

p-tertiary amylphenol 7.4

200.0 INTRODUCTION

200.1 USE(S):

Refer to the attached labeling for specific uses.

200.2 BACKGROUND INFORMATION

The submission, received August 23, 1996, is for review of Use-Dilution efficacy data performed for the Antimicrobial Testing Program by North Carolina Department of Agriculture's (NCDA) Microbiology Lab.

201.0 DATA SUMMARY

201.1 BRIEF DESCRIPTION OF TESTS

AOAC Use-Dilution Test results by Amoret D. Bittle, North Carolina Department of Agriculture, Microbiology Laboratory, 4000 Reedy Creek Road, Raleigh, North Carolina 27607, dated August 9, 1996.

201.2 TEST SUMMARIES

Use-Dilution Test

Method: AOAC Use-Dilution Method, 15th Edition, 1990, Chapter 6, Sections 955.15 & 964.02.

Modifications: 400 ppm hard water and
5% bovine albumin fraction V

Sample Number

Dates Tested

042596F28950107B
Batch: 210323

7-1-96, 7-25-96

Dilution: 1:256

Exposure: 10 minutes at 20°C

Subculture Medium: Lethen Broth

Incubation of Subcultures: 48 hrs. at 37°C

TEST ORGANISMS

ATCC No.

Phenol Resistance

Staphylococcus aureus

6538

1:60

Pseudomonas aeruginosa

15442

1:80

Carriers Tested: Stainless Steel cylinders

202.0 RECOMMENDATIONS

202.1 EFFICACY SUPPORTED BY THE DATA

The submitted data for sample # 042596F28950106B Batch:210322 tested by the Use-Dilution Method at the NCDA Microbiology Lab, demonstrate the effectiveness of the product as a hospital disinfectant when diluted 1:256 in hard water (500 ppm as CaCO_3) in the presence of organic soil (bovine albumin fraction V) against S. aureus and P. aeruginosa for a contact time of 10 minutes at 20°C.

TEST RESULTS: Sample #042596F28950106B Batch:210322

<u>ORGANISM</u>	<u>DATE TESTED</u>	<u>NO.+/TOTAL TESTED</u>
<u>S. aureus</u>	7-1-96	1/60
<u>P. aeruginosa</u>	7-25-96	0/60

CONCLUSIONS

This sample of the product was effective against S. aureus and P. aeruginosa at a 1:256 dilution in hard water (500 ppm as CaCO_3) in the presence of organic soil (5% bovine albumin fraction V) when tested by the AOAC Use-Dilution Method for a contact time of 10 minutes at 20°C.

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

ANTIMICROBIAL PROGRAM BRANCH

EFFICACY REVIEW - FORM 2

EPA Registration: 1043-92

Date EPA Received: August 23, 1996

Date RD Received: August 23, 1996

Project Return Date: February 19, 1997

Review Start Date: September 6, 1996

Review Completion Date: September 6, 1996

MRID No(s): NONE

Product Manager & Team No.: PM - 32 (D. Aviado)

Product Name: LpH se

Company Name: Convatec Div. of E.R. Squibb & Sons, Inc.

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

ANTIMICROBIAL PROGRAM BRANCH

EFFICACY REVIEW - FORM 2

EPA Registration: 1043-92

Date EPA Received: August 23, 1996

Date RD Received: August 23, 1996

Project Return Date: February 19, 1997

Review Start Date: September 6, 1996

Review Completion Date: September 6, 1996

MRID No(s): NONE

Product Manager & Team No.: PM - 32 (D. Aviado)

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<u>ORGANISM</u>	<u>DATE TESTED</u>	<u>NO.+/TOTAL TESTED</u>
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<u>P. aeruginosa</u>	7-25-96	1/60

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